



K 970631

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SECTION 5 - 510(K) SUMMARY

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By: Raymond G. Wallace

Trade Name: Punctal Occluder

Common Name: Punctum Plugs

Classification Name: Punctum Plugs (per 21 CFR § 886)

Summary:

This device, made of medical grade silicone and titanium dioxide as a colorant under current good manufacturing practices, is a small, generally "plug" shaped design. Punctal Occluders are intended for the treatment of "dry eye" conditions through the total occlusion of individual punctal openings.

By material, design and intended use, the Odyssey Punctal Occluder is substantially equivalent to the pre-amendment EV - Freeman Punctum Plug.

Differences between the two devices may be described as follows:

1. The Eagle Vision plug has a slight "taper" which they have patent protection on, however, their pre-amendment device has no such "taper" and is identical to the Odyssey device. The claims made by Eagle Vision in favor of the "tapered shaft" have no known data to support them and no 510(k) to suggest that the design change is significant enough to warrant it.
2. The titanium dioxide present in both devices is used as a colorant. As such, it is Odyssey's opinion that less titanium dioxide does not hinder the visibility of the device.

Alternative methods are either permanent or difficult to reverse. In contrast, the submitted method is both functionally safe and fully reversible. Unlike some other methods, this device does not require the breach of intact tissue surfaces nor the risk of damaging said surfaces should reversal become desirable.